

#### Working to expand ESG, a management issue

With a corporate philosophy of "always putting healthier lives first," the Group is aiming to provide healthy lives. As is clearly stated in our key sustainability policies, a healthy society and its sustainable development are the foundation of why we exist.

I was involved in formulating these key policies in 2021, but I had started to think about the relation between the ideal form of corporate activity and society when I was young. During my time at the secretariat of a particular business organization, I came across the idea that "business activities are circular like the natural environment, and both one's own company and society will prosper through the cycle of using profits to expand production, not fighting to capture more of the pie." Sustainability activities demanded of companies and this idea are connected at their roots.

#### Working to lessen the environmental burden caused by production activities

As for our environment (E) initiatives, until then, the Company had focused on reinforcing its production capacity with the goal of providing a stable supply of generic drugs, but consideration of the environmental burden caused by production activities was not necessarily sufficient.

Taking this point into consideration, in fiscal 2022, we revised the environmental targets in the Medium-Term Business Plan. After examining concrete measures to reduce CO<sub>2</sub> emissions, we switched the Group targets to emission volume from emission intensity per unit of production, and then set the numerical target of reducing 2030 emissions 46% compared to fiscal 2013 +  $\alpha$  (see page 33). One example of our steady initiatives should be to focus on further recycling waste plastics that were used as packaging.

#### Steadily moving forward with initiatives to ensure diversity and investments in human capital

As for the field of society (S), one of the things that I have wanted to do for several years is to promote inclusion, diversity, and equity (ID&E).

While around one-third of the Group's employees are female, women make up a small percentage of managers, and we have failed to reach our target of 8% of managers being women. Therefore, in fiscal 2022, we gathered employees interested in the topic and launched a project team, which compiled proposals for management (see Topics on page 30). We plan to establish a new body in the near future so that we can move from these proposals to action. Raising the percentage of managers who are women, one of the goals for promoting ID&E, will result in a natural improvement in the wage differences between men and women.

As for developing talent, we have traditionally worked to expand training options so that employees can take courses appropriate for their individual interest, awareness, career plan, and other aspect. By offering not only traditional group training and correspondence training but also a wide range of options linked to independent professional organizations, we have raised the annual number of training sessions per employee to 1.4 times. In the future, I would like to add more training options for management candidates.

In fiscal 2022, we also launched new measures related to developing successors. The Group has a system in which each employee creates and submits a goal sheet once every six months, and for all levels of line managers, we have introduced a system in which 20% of goals are related to developing successors. Under this system, managers set goals for succession planning and manage progress.

#### Two governance reforms

Since transitioning to a holding company, we have steadily made progress in raising our level of governance. As a result, we have expanded the four committees (Risk Management Committee, Compliance Committee, Information Security Committee, and Sustainability Committee) throughout the Group, creating a system in which people tackle issues with a sense of unity.

We implemented two major reforms in fiscal 2022. The first one was establishing a framework for succession plans for such officers as CEO. The second one was appointing external directors with management experience for the first time. As a result, external directors account for 50% of directors. By steadily implementing these initiatives and conducting quite thorough deliberations regarding the Board of Directors, I think that we are getting close to having the Board of Directors that we should have.

#### Launch of initiatives to spread ESG awareness

An important issue is spreading ESG awareness among employees. Therefore, since fiscal 2022, we have included an ESG perspective when selecting small-group activity topics in Japan. Although this was the first year, we have already had several successes, such as some factories giving presentations on results related to "transforming operations into ones that impose less of an environmental burden by increasing energy efficiency." There also seems to be a good response to using the in-house intranet, too, to frequently explain in-house activities and introduce a bottom-up approach, not a top-down one.

#### Building strong bonds with all stakeholders and aiming for sustainable growth

As stated at the beginning, it is impossible for the Group to grow on its own. For us, sustainability is building bonds and growing with all stakeholders, not only patients and healthcare professionals but also local communities and global environment.

The Group's corporate philosophy and corporate culture must be valued in order to promote this sustainability. Our employees who joined the Company because they identify with our corporate philosophy and value connections with society are one of our strengths, and it is my duty to further improve the Group's strong efforts related to ESG, the foundation of sustainability, to a level that they are recognized. The goal is to create a corporate group in which all employees work together and generate sustainable growth with society over the long term.

#### Main initiatives in ESG fields

Issues to address	Targets (quantitative/etc.)	FY2022 Results
E Environmentally friendly production	<ul> <li>Reduce CO<sub>2</sub> emissions by 46% in FY2030 on a gross volume basis (based on FY 2013 emissions + α)</li> <li>Net zero CO<sub>2</sub> emissions by 2050</li> <li>Waste plastic recycling rate of 65% or more (in 2030)</li> </ul>	<ul> <li>Changes and additions to medium term management plan environmental targets.</li> <li>Consideration of installing solar power panels installed at Kyushu Daini Factory.</li> <li>Started power generation using solar power generation panels at the Sanda Nishi Factory (FY2022 power generation: 5.9% of annual electricity used by the plant).</li> </ul>
S Talent development, work styles / motivation, respect for human rights	Safe and diverse work environment	Transition from a telecommuting system used during the COVID-19 pandemic to a permanent telecommuting system.  Use of stress check results for workplace improvement.  Conducting employee engagement survey and interview survey (examine measures for the coming fiscal year).
8 DECENT WORK AND COUNTY GROWTH TO DECUMENTS	Promotion of diversity	Action plan proposal to promote ID&E for the in-house project established taking into consideration the results of that gender awareness survey conducted in house.
	Initiatives for respect of human rights	Compliance e-learning on harassment.     ID&E Initiatives based on engagement survey (Upsher-Smith).
G Deepening corporate governance	Improvement and deepening of governance through conversion to holding company structure	Direct reporting and explanation at the Board of Directors meetings about various committees which include related members.     Started developing succession plans for CEO and other officials by Nomination, Remuneration and Other Governance Committee
17 PARMETSHE'S FOR THE GOILES	Stronger risk management / compliance	Implementation of E-learning on compliance, information security, etc.     Strengthening information security governance, such as obtaining ISMS certification (ISO27001) and targeted mail based training.

### **Message from General Manager of Group Human Resource Department**

Promoting efforts to secure and train diverse human assets indispensable for our growth strategy

#### **Fumilito Yamakawa**

General Manager of Group Human Resource Department



#### Promoting a human asset strategy based on the Medium-Term Business Plan

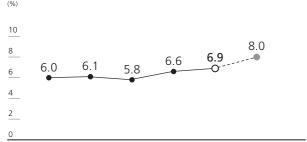
In the three-year Medium-Term Business Plan START 2024, we set the goals of further strengthening our generic drug business and entering into new business in different growth fields. To further strengthen the generic drug business, we must be the first to release and provide a stable supply of high-quality, high-value-added products, and what is particularly vital is strengthening our R&D and production functions. We must also possess creative, transformative human assets with unconventional ideas to promote new businesses in fields unknown to us.

We are working to secure and train outstanding human assets with diverse ways of thinking under the basic human resources philosophy of "fostering and leveraging the individual" with these types of business in mind.

While Japan's labor market continues to be a seller's market because of a shortage of workers, Sawai Pharmaceutical aggressively conducted recruiting in fiscal 2022 and hired 230 new employees, which includes new graduates. We also reinforced our R&D and production

(scope: Sawai Pharmaceutical)

Ratio of female employees in managerial positions



2021

2022

2020

functions by adding about 400 employees, mainly R&D and manufacturing workers, from Trust Pharmatech, which joined the Group in April 2022.

As for human asset training, the main Group companies in Japan are working to create a system of employee evaluations and training, and one related initiative was preparing "skill requirement definition documents," which stipulate items such as the skills and expected role for each job and grade. To achieve highly creative organization management, we are focusing on cultivating a culture of diversity that values diverse ways of thinking regardless of sex or age.

#### Valuing individuality and creativity and reinforcing engagement

In a seller's labor market, retaining human assets is an issue for all companies, including us. Regarding this point, we value the individuality and creativity of each employee and work to strengthen employee engagement based on our basic human resources philosophy. Main Group companies in Japan offer opportunities for superiors and subordinates

Turnover rate (scope: Sawai Pharmaceutical) 10 3.1 2019 2021 2022

to hold one-on-one discussions on such issues as performance and career several times a year, and it is our opinion that this contributes to greater motivation, an open work environment, and thus employee retention. Furthermore, on the in-house Intranet, which all employees can access, we provide not only management information, such as business plans and management figures, but also the thoughts of and daily routines of senior management.

These initiatives have been successful, and for many years, Sawai Pharmaceutical has been able to keep our employee turnover rate to less than 10%, while there are surveys that indicate a turnover rate of more than 30% for new graduate recruits over their first three years of work.

#### Cultivating a corporate culture of mutual acceptance of diverse values

We consider fostering a corporate culture in which people mutually accept various values and backgrounds an important element for growing the Company and individuals. At Sawai Pharmaceutical, which is aiming to become a company in which anyone, not limited by their sex, handicap, or other issue, can play an active role, one of the goals is to achieve the goal of having women account for at least 8% of managers and employees with disabilities account for at least 2.3% of our workforce by the end of fiscal 2023.

Furthermore, in July 2022, a company-wide project, composed of members from the various Group companies, was launched to examine measures to promote inclusion

and diversity. Because of this project, many issues for examination were proposed, such as providing training to transform the awareness of employees, including management, and we will develop concrete policies and a system to promote related initiatives in the future.

#### Focusing on promoting health and productivity management based on the corporate philosophy

Touting the corporate philosophy of "always putting healthier lives first" and with the idea that "better drugs are born from workplaces that are both mentally and physically healthy," we are focused on creating an environment in which employees can work while maintaining their health.

We create an annual physical and mental health promotion plan and boast a system to implement that plan, and our main business offices in Japan offer an environment in which the physical and mental problems of employees can be guickly dealt with in collaboration with an occupational physician. Furthermore, so that all employees can enjoy their work, we are striving to eliminate harassment by clearly stating the corporate stance of ending harassment through employment rules and other items and operating a harassment helpline.

Because of these efforts, we were selected by the Ministry of Economy Trade and Industry—as a "Certified Health & Productivity Management Outstanding Organizations." We hope to continue to focus on promoting health and productivity management.

### Topics

#### Action plan proposal to promote ID&E through an in-house project

The project was initially launched in July 2022 as the "Active Participation of Women Promotion Project" (tentative name), but based on the collective opinion of project members, related activities were broadened from ones only targeting women to ones for all employees. Furthermore, the project was named S-Wing, which embodies the idea of making it possible for Sawai (S) to move forward and offer pleasant workstyles without a bias in the "wings" that support us.

Because of an imbalance in the ratio of male and female project members, during the almost nine months of project activities, around thirty new projects members were added as ambassadors in order to incorporate opinions regardless of gender. This made it possible to undertake activities that incorporate various perspectives. In March 2023, an action plan proposal regarding all employee activities was submitted to senior management. In response to the proposal, the Group will continue to promote inclusion, diversity, and equity (ID&E).





#### S-Wing Project

https://www.sawai.co.jp/sawai-gender-action/ project.html (Japanese language only)

Note: We use the term "ID&E" because we consider inclusion (I) an important foundation for promoting diversity (D), but also view equity (E) as an essential related idea.

2019

ESG data: https://global.sawaigroup.holdings/sustainability/esg/ **SASB index:** https://global.sawaigroup.holdings/sustainability/sasb/

# Society

#### Quality management

#### Sawai Pharmaceutical

By conducting unannounced audits each year, Sawai Pharmaceutical confirms that its factories can pass inspections by government authorities whenever they may occur. Similarly, Trust Pharmatech's manufacturing locations, where operations were newly launched in fiscal 2022, are managed at the same level as Sawai Pharmaceutical factories, and similar audits have been started.

In terms of the quality of APIs, we rigorously check whether each manufacturing factory complies with Good Manufacturing Practices (GMP) stipulated by law using our own standards by conducting onsite verifications, etc. of

API manufacturing sites for some 300 ingredients (a total of approximately 500 manufacturing sites), and only use APIs that have passed the verifications.





#### **Quality management (Sawai Pharmaceutical)**

https://www.sawai.co.jp/medicine/sawaigenerics/quality/ (Japanese language only)

#### Main items

- API quality Quality management system at factories
- Response to PIC/S Conduct drug use-results surveys

#### Video explaining quality-related initiatives (Sawai Pharmaceutical)

https://www.sawai.co.jp/medicine/sawaigenerics/ quality\_movies/ (Japanese language only)

#### Upsher-Smith

Upsher-Smith consistently manufactures products of permissible quality by undertaking production and quality management in line with the quality management system (QMS) required by U.S. government regulations.

For all raw materials and final products, the Company conducts testing in line with FDA approval standards. Furthermore, a comprehensive evaluation of final products is conducted using an annual product review.

The Company also makes comprehensive self-checks of equipment/systems regularly in line with the in-house procedure manual. At new factories, electronic batch records are being introduced to further increase quality.

#### Preventing counterfeit pharmaceuticals

#### Upsher-Smith

Upsher-Smith and its pharmaceutical supply chain are promoting initiatives required under the Drug Supply Chain Security Act (DSCSA). The requirements under the DSCSA establish a chain of custody for each saleable unit (primarily bottles/blisters) in accordance with the Act.

As the deadline for becoming serialization compliant is November 27, 2023, the Company is moving forward with related preparations. Furthermore, for all our bottles, the seal clearly indicates if it was improperly opened.

### **Communication with patients**

#### Sawai Pharmaceutical

#### **Patient Support Office**

Sawai Pharmaceutical's Patient Support Office is the only in-house department permitted to directly communicate with patients. Because many inquiries by patients are due to vaque concerns about treatment and medicine, the Patient Support Office first works to accept those concerns.

The goal is to alleviate the worries of patients, which helps them be more positive about their treatment and move forward with appropriate treatment.

#### Sawai Kenko Suishinka, Website for general population

Our corporate website offers knowledge and information that helps patients find peace of mind regarding drugs, and this information includes basic information on generic drugs and our quality initiatives. We also post a variety of healthcare-related information, including information on pre-disease and preventive measures, disease awareness, and health promotion through pages called Sawai Kenko Suishinka.

If using the PHR management application SaluDi to keep PHR, it is possible to easily access the Sawai Kenko Suishinka from within the app.



Top page of Sawai Kenko language only)

### **Human rights and human resources**

The Sawai Group has established a Code of Conduct to define its approaches toward respect for human rights, consideration for the health and working environment of employees, and fair and appropriate treatment of employees. In line with the code, the Group is actively and proactively addressing these issues.

Details of policies and initiatives are reported on the website.

#### **Human rights and human resources**

https://global.sawaigroup.holdings/sustainability/human/

- Initiatives to respect human
- Consideration for the health and the working environment of employees
- Consideration for employees' nursing care, childbirth and
- Fair and appropriate · Enhancing diversity
- Policy on human asset
- development · Training system Policy on ensuring
- Percentage of paid leave days used

Disclosed data

- Number of employees taking nursing care leave, maternity leave, or childcare leave
- Percentage of female managers (Sawai pharmaceutical only)

workplace diversity

- Percentage of employees with disabilities (Sawai pharmaceutical only)
- Number of participants in

## Policy on respect for human rights

As a healthcare corporate group closely related to life, our Group is committed to respecting the human rights of various stakeholders, including patients, employees in Japan and overseas, and business partners, and supports the International Bill of Human Rights and the International Labor Organization's Declaration on Fundamental Principles and Rights at Work, and promotes initiatives in accordance with the United Nations Guiding Principles on Business and Human Rights.

#### Sawai Pharmaceutical Group companies in Japan

In the Group companies in Japan, we recognize employees and labor unions as important stakeholders and maintain sound and good labor-management relations. In addition, we are striving to raise awareness of human rights by clearly stating in our Code of Conduct that we oppose any form of discrimination on the basis of race, gender, nationality, ethnicity, religion, ideology, political opinion, sexual orientation, disease, disability, and refuse any involvement in the infringement of human rights.

#### **Upsher-Smith** Overseas Group companies

Since our overseas Group companies are more racially diverse than the Group companies in Japan, they devote special efforts to respect for diversity, including racial diversity, which they recognize as an important social issue. At Upsher-Smith Laboratories (USL), a Group Company based in Minnesota, where the Black Lives Matter movement in 2020 originated, members of senior management have taken the initiative with the belief that the diversity of employees is a source of the Company's strengths and greater performance. In addition, the advisory council related to four minorities (Blacks, women, Southern Asians, and Hispanics) on four minority groups (Blacks, Women, South Asians, and Hispanics) meets regularly to identify the potential biases of employees and devise measures to increase mutual understanding between them, and the Employee Resource Group is working on women and LGBTQ+ issues.

#### **Employee engagement survey**

In 2022, the Group conducted an employee engagement survey, which is conducted every several years. The results confirmed not only that employees possess a stronger sense of identification with the Company and its management policies compared to the previous survey but also that we have maintained a high level of satisfaction as an employer. We consider this proof that even in the harsh business environment in recent years, employees are conducting their work with a sense of pride in and responsibility for providing generic drugs.

However, there were signs of a decline in collaboration between departments and sense of mutual help. Through this survey, we confirmed that there is engagement with the Company and work but also that there are issues, such as employees feeling stress regarding greater work volume and difficulty of their work and employees having a low desire to take on challenges because they are busy with the work in front of them.

These issues were reported to the Management Meeting and improvements were deliberated on. A summary of this is shared with employees via the in-house Intranet. We will continue to conduct this survey because it leads to a stronger sense of unity and engagement by delivering employee opinions to management and resolving problems.

ESG Data: https://global.sawaigroup.holdings/sustainability/esg/ Disclosure Based on TCFD Recommendations (details): https://global.sawaigroup.holdings/sustainability/tcfd/

## **Environment**

#### Review of environmental targets in **Medium-Term Business Plan**

#### Raised CO<sub>2</sub> emission reduction targets

Of the various environmental targets in the Medium-Term Business Plan START 2024 (April 2021–March 2024), we partially revised our targets related to CO2 emissions. The goal of these revisions was to align the target level with the government's goal of Carbon Neutrality by 2050 and reinforce initiatives to cut CO<sub>2</sub> emissions to achieve the target of "cutting CO2 emissions 46% compared to FY2013 by FY2030."

The revisions were approved after deliberations by Sawai Pharmaceutical's Sustainability Committee, the Group Sustainability Committee, Group Strategy Council, and Board of Directors. The main revisions are given in the following table.

#### Main revisions

Previous

Type	Risk overview	Impacts on the
Risks and opportuni	ties related to clin	nate change (period:
Reduce emissions 25% intensity-per-unit-of-pro basis by FY2030		

#### **Disclosure based on TCFD** recommendations (summary)

#### Governance

- The Group COO was assigned responsibility to address climate change issues and the Board of Directors oversees the performance of those duties.
- The Group Sustainability Committee (chaired by Group COO), which is composed of representatives from each Group company, meets four times a year to discuss and examine sustainability-related matters, including climate change issues. Regular reports are made to the Board of Directors, and decisions are made under the direction and oversight of the Board of Directors.
- Global Environment Team, a subordinate body of the Committee composed of members from each Group company, was established, and reports to the Committee quarterly.
- The envisioned risks and opportunities are as in the following table.
- A Sustainability Committee, chaired by the President and Representative Director, was also established at Sawai Pharmaceutical, the Group's core company, and meets four times a year.

#### fiscal 2021-fiscal 2030)

Revised

	Ŧ		Risk overview	Impacts on the Group's businesses, strategy, and financial planning	Magnitude of impacts		The Group's methods
Туре		туре			1.5°C scenario	4.0°C scenario	for addressing climate-related risks
Risks	Transition	Policy and legal risks	Introduction of carbon pricing (a carbon tax and an emissions trading scheme) and the resulting increased burdens	Burden on the Group created by carbon pricing Need to pass on the carbon-pricing-created financial burdens of suppliers with high GHG emissions to the Group's purchase prices of raw materials  Burden on the Group of capital investment in energy saving necessary to reduce its GHG emissions	Moderate	Minor	Considering the introduction of renewable energy     Devising and implementing measures to enhance production efficiency, including reducing waste products
	Ę.	Population, economic, and geopolitical risks	Price hike for bio-derived raw materials due to population growth and temperature increases	<ul> <li>Population growth especially in emerging economies will cause an increase in the prices of grain and grain-based products (starch, sucrose, corn, etc.) for food, feed, and other uses and consequently in the prices of raw materials of additives for pharmaceutical products</li> </ul>	Minor	Moderate	Diversifying suppliers     Studying alternative technologies
	Physical risks	Flood risks (acute risks)	Increased frequency of typhoons, torrential rains, floods, etc.	Increased risk of damage to the Group's business sites     Increased risk of damage to the business sites of the Group's suppliers	Minor	Major	Sandbagging the areas where product inventories are stored     Obtaining damage insurance coverage     Formulating BCPs for the Group and its supply chain
Opportunities		portunities		rsis and evaluation of climate-related opportunities that ca ortunities that can have significant impacts on the Group's			

**Scope of coverage** Sawai Group excluding Trust Pharmatech and Upsher-Smith

Impact classification Major: Major impacts on the Group's businesses, strategy, and financial planning that the Group estimates to be worth approximately ¥6.0 billion or more; Moderate: Moderate impacts on the Group's businesses, strategy, and financial planning that the Group estimates to be worth approximately ¥3.0 billion or more Minor: Minor impacts on the Group's businesses, strategy, and financial planning that the Group estimates to be worth approximately less than ¥3.0 billion

#### Strategy

- Work to reduce emissions intensity in the short term.
- Work to reduce emissions, including examining introducing non-fossil energy, in the medium and long term.
- Examine the impact on the Group using various scenarios, including the 1.5°C, which assumes the increase in average global temperatures since the industrial revolution is limited to less than 2°C, and the 4°C scenario, which assumes average global temperature rise as GHG emissions continue to increase because government policies and regulations basically remain unchanged from the current ones.

#### Risk management

- Screen, evaluate, and identify risks with the participation and collaboration of in-house divisions and affiliated companies strongly connected to each stage of the supply chain, with the Global Environment Team playing a core role.
- Have Group Sustainability Committee and Board of Directors examine and deliberate on risks and then make related decisions based on the evaluation results.

• Have the Board of Directors appropriately include this in the annual business plan in the short term and Mediumterm Business Plan in the medium and long term.

#### **Metrics and targets**

• The following metrics and targets have been set, and progress in achieving them is managed.

Metric	Target	
	(Single fiscal year) Reduce scope 1 and scope 2 emissions at least 1% compared to the previous year	
(1) GHG emissions, including CO₂	(Medium-term) Reduce total CO <sub>2</sub> emissions (scope 1 and 2) 46% compared to FY2013+α level by FY2030	
(scope 1 and 2)	(Long-term) Achieve net zero by 2050	
	* Disclose annual reductions for each scope on the corporate website.	
(2) State of planned introduction of non-fossil energy	Introduce non-fossil energy equivalent to a certain reduction in CO2 emissions each year proportional to actual emissions in order to achieve fiscal 2030 target	

## **Topics**

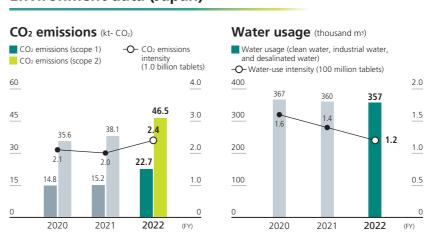
### Achieving energy-efficient operations by controlling air pressure differential between rooms

At pharmaceutical factories, appropriately setting the air pressure differential between rooms traps airborne granular material in the room and prevents cross contamination (mixing of different items). Because it is difficult to appropriately control the air pressure differential between rooms, ventilation equipment has traditionally been operated even on days factories are closed, but by properly adjusting such equipment as ventilation ducts and inverters for each room, it is possible to operate in an energy efficient mode.

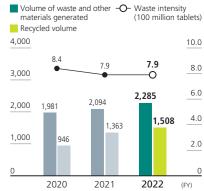


Air-conditioning equipment for which operating time was successfully reduced by revising how it is used

#### **Environment data (Japan)**



#### Volume of waste and other materials generated (tons)



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Navigating a turning point in the generic drug industry and providing a stable supply of high quality drugs

#### **Motohiko Kimura**

Senior Managing Executive Officer Representative Director and President of Sawai Pharmaceutical Co., Ltd.

#### **SWOT** analysis

#### Strengths

- One of the top supply capabilities in Japan
- Proprietary product development capabilities
- Brand strength as top manufacturer
- Stable financial base
- Integrity of employees based on corporate philosophy

#### **Opportunities**

- Chance to restructure the generic drug industry
  Growing demand because of aging
- society

   Diversification and growing
- Diversification and growing sophistication of healthcare and medicine needs

- Takes time to train and secure employees as demand grows
- Difficult for management to decide to suspend sales as many unprofitable products have top shares

#### Threats

Weaknesses

- Decline in drug prices for various reasons including annual drug price revisions
- Decline in trust in generic drugs
- Increase in launch of AGs
- Weak growth in advanced countries
- Increase in raw material costs

#### Revenue / Core operating profit



#### Sawai Group Vision 2030 quantitative targets

	FY2020 (actual)	FY2022 (actual)	FY2030 (target)
Revenue	¥153.6 billion	¥163.7 billion	¥260.0 billion
Sales volume	13.3 billion tablets	15.0 billion tablets	20.0 billion tablets
Share of sales	15.7%	16.0%	20.0% or more
Production capacity	15.5 billion tablets	18.5 billion tablets	23.0 billion tablets or more

# On assuming the position of Sawai Pharmaceutical President—responding to change by melding the strengths of each in-house divisions

My name is Motohiko Kimura and I am the new Representative Director and President of Sawai Pharmaceutical. Before entering the Company in 2016, I worked in the department responsible for coordinating production at Sumitomo Pharmaceuticals (currently Sumitomo Pharma). Before that, I worked on biopharmaceutical research and gained experience in various divisions, including ones involved in the launch of a commercial cell cultivation plant, sales and purchase of intellectual property, business development, and purchasing. When I was stationed in Europe, I also helped launch an English corporation. At Sawai Pharmaceutical, as the Senior Vice President of the Manufacturing Division since 2017, I pushed forward efforts related to restructuring and strengthening the production system at each factory and increasing their production capacity. I was appointed president in order to leverage these experiences and contribute to guick solutions to problems related to guality and stable supply, which are demanded of the generic drug industry.

The Company is now approaching a turning point. In addition to annual drug price revisions, increases in raw material costs, and a duty to provide a stable supply of our GE new products, development is growing more difficult due to the growing complexity of formulation. Despite releasing new products, we have been unable to halt the increase in the number of unprofitable products. AGs are also growing in number, making it an extremely difficult time. Furthermore, this is a period of numerous expected changes, including the Ministry of Health, Labour and Welfare launching a working group on system reforms, and we must properly respond to these changes.

Under these conditions, the management and marketing strategies are important, and it is time for each

division to collaborate even closer with each other and for us to rebuild our system so that we can quickly respond to change.

Because we produce an extremely large number of generic drugs, we face different production difficulties than those of drug manufacturers that produce a small number of new drugs, and these difficulties include having to routinely change production equipment.

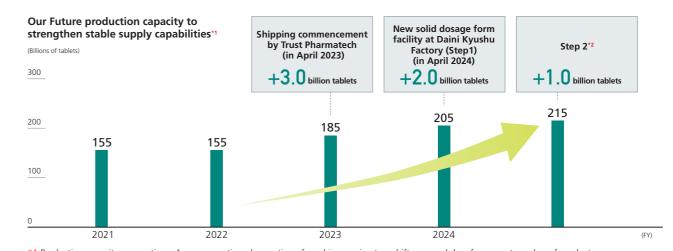
One of my responsibilities is to link not only research to production but also marketing to production by formulating a strategy and leading them like an orchestra conductor. This makes it possible for work to progress smoothly both inside and outside the Company. I would like to leverage my skillful footwork, one of my strengths, for that.

## Taking on the challenge of implementing various measures to transform difficulties into opportunities

In fiscal 2022, we recorded revenue of ¥163,702 million from the Japan generic drug business because despite the impact of drug price revisions, sales of new products grew, and we lifted limits on shipments. On the other hand, core operating profit fell year on year to ¥21,425 million because of upfront investments and higher costs.

Furthermore, we project a decline in profit for fiscal 2023. The main reason for this decline is higher costs. Although we have lowered production costs each year after I became the Senior Vice President of the Manufacturing Division, fiscal 2022 was the first year that it was not possible to cover drug price revisions with lower production costs. This was because of the impact of the war in Ukraine, and higher labor and heating and lighting costs. For example, products that cost ¥100 in the previous year cost ¥105 this year, an overall 5% increase in costs.

In response to this increase in costs, we worked to further raise productivity and reflect the impact of those higher costs in prices. We have requested the understanding



- \*1 Production capacity assumptions: Assumes continued operation of machinery using two shifts on weekdays for current number of products. Does not include outsourcing.
- \*2 Step 2: Timing undecided

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of wholesalers and retailers in fiscal 2023, too.

Under these conditions, we must take these kinds of steps so that we can fulfill our responsibility to continue to deliver required drugs, even unprofitable ones, to patients. In this type of situation, what is important is properly fulfilling our responsibility to be accountable to business partners. In my previous position as Manager of the Purchasing Department, the most important thing was to fully explain the Company's current situation before requesting cooperation. Greater understanding not only raises the level of cooperation but also leads to trust. I consider it my role as head of the Company to continue this type of dialogue.

Furthermore, there previously were few exchanges among companies in the generic drug industry. I think that we can build a relationship of mutual prosperity beneficial to all through even deeper collaboration with stakeholders, including business partners and suppliers. Fortunately, there are extremely high expectations for the Company, which boasts the largest market share in the industry, and I want to examine what type of collaboration is possible through consultations with the Chairman of the Board and Vice Chairman.

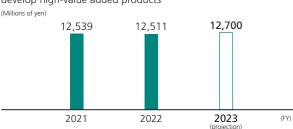
# Moving forward with both increasing production capacity and securing and training people in order to further increase our share

Following an almost yearlong preparatory period, Trust Pharmatech started to ship products fully produced in-house in June 2023 as scheduled in order to eliminate supply shortages and increase production capacity. Furthermore, at the Daini Kyushu Factory, construction of a new solid dosage form facility is moving with the goal of launching production activities in April 2024. This will make it possible to increase our production capacity to more than 20.0 billion tablets in fiscal 2024.

There is a need to improve the capabilities of production facilities, which would also resolve the issue of it being more difficult to commercialize new products. This is because it is necessary to possess spare production capacity and launch commercial production—scale tests at

#### **R&D** expenses

More than ¥10.0 billion annually in R&D expenses to develop high-value added products



the factory as quickly as possible so that we can swiftly transition to stable production. First of all, we will focus on launching full production at Trust Pharmatech and completing the new facility at the Daini Kyushu factory.

While our current share of the Japanese generic drug market is about 16% on a volume basis, the long-term vision for 2030 includes a target market share of 20% or more. It is, however, my opinion that the mission of the Company is to increase our market share beyond that.

To do that, it is important to recruit and train people. We not only stress the turnover rate as a KPI, but have also introduced a system in which more senior employees close to the age of new recruits are assigned as mentors, who serve as advisors and pass on their experience along with work guidance. Through these efforts, we lowered the employee turnover rate to 3.1% in fiscal 2022 from 4.8% in fiscal 2017. Having employees remain at the Company will also increase the capabilities of each and every employee. In addition to a system in which a single employee handles multiple operations, we are introducing KPI and a numerical scale for work skill ranks.

Because of these efforts, since 2017, the year I became the Senior Vice President of the Manufacturing Division, our production volume has increased 1.6-fold without substantially increasing the number of employees.

## Creating a "company that continues to contribute to society far into the future" by leveraging our strengths

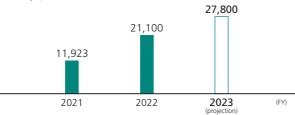
One of Sawai Pharmaceutical's strengths is its corporate philosophy of "always putting patients first." We are proud of the fact that we are all moving in the same direction under this philosophy and are unsurpassed in the speed of our response. My goal is to transform the Company into a "company that continues to contribute to society far into the future." While consulting with everyone regarding what should be done to achieve that and deliberating with stakeholders both in and outside the Company, we will move forward with management so that we can win people's trust.

Moto. Kemura

Senior Managing Executive Officer Representative Director and President of Sawai Pharmaceutical Co., Ltd.

#### Capital expenditures

¥60.0 billion in capital expenditures over three years from fiscal 2021 to increase production capacity





# FY2022 Marks a turning point for Upsher-Smith

-looking to build on momentum from strong FY2022 performance-

#### **Rich Fisher**

President & COO, Upsher-Smith Laboratories

#### SWOT analysis

#### Strengths

- Consistent high quality supply from manufacturing facilities located in the U.S.
- Strong relationships with major wholesalers
- High level of employee engagement
   Strong development partnerships with
- Strong development partnerships with outside partners

#### **Opportunities**

- High population growth rate for an advanced country
- Size of the market, which accounts for about 40% of the global market
- Supply disruptions of competitors that struggle to comply with regulations and raise funds

#### Weaknesses

• Lower relative price competitiveness compared to Indian companies

#### Threats

- Excessive decline in selling price due to competition with new entrants
- Continuing pricing pressures driven by consolidation into three major purchasing groups

#### Revenue / Core operating profit



#### FY2022 performance

My name is Rich Fisher and I assumed the role of President and COO of Upsher-Smith Laboratories (USL) approximately one year ago. Despite the continuation of challenging conditions in the U.S. generic market, USL had an outstanding year. FY2022 marked USL's first year-over-year revenue increase in nearly a decade and USL also achieved substantive improvements in profitability. We expect additional revenue and profitability growth in FY2023. Growth in FY2023 will be driven primarily by a significant number of new product launches, which will more than offset expected revenue declines for mature products. USL's external R&D model, which was implemented over a year ago, has been a spectacular success, leading to a dramatic decrease in expense and an increase in pipeline products, submissions to FDA, and new product launches.

#### Investing in human resources for future growth

Shortages of workers in production areas continue to be a challenge, with unemployment in MN remaining at historic lows of approximately 3%. USL continues to aggressively recruit and work on initiatives important to employees such as Diversity, Equity and Inclusion. In FY2022, USL increased the diversity pool of candidates for new jobs, implemented

new training tools, and expanded activities associated with Employee Resource Groups. Despite worker shortages, significant milestones were achieved in FY2022.

#### **Outlook for FY2023**

USL's new 25,000 square meter manufacturing facility was approved by the FDA late in 2022 and began commercial manufacturing in February of 2023. The outlook for FY2023 and beyond looks promising. USL has a strong reputation in the U.S. for consistently delivering quality products. Some of USL's competitors have stumbled due to 1) lack of regulatory compliance, leading to importation bans into the U.S. 2) Financial difficulties, leading to bankruptcy filings and inability to continue to market their products 3) Insufficient investments in operations, leading to potential non-compliance with pending serialization and aggregation requirements. It is possible that these developments mark a turning point in the U.S. generic industry, and USL is very well-positioned to capitalize on competitor's failures.

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# **Developing new business** fields to evolve into a general healthcare company

To achieve sustainable growth for the Group, we will work to not only strengthen our existing generic drug business but also foster new businesses. Our goal is to possess a strong presence and continue to contribute to people's health by creating a world where more people can receive healthcare services and live a full life with peace of mind among society, and providing a multifaceted mix of products and services based on scientific evidence that meet individual needs.

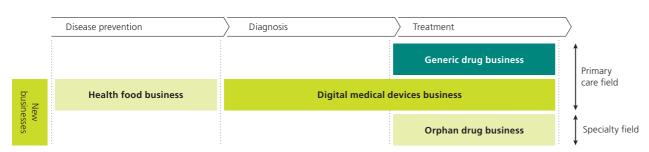
#### **Target business fields**

Taking into consideration the ideas of contributing as a general healthcare group that provides healthy lives to the creation of a society with health longevity through pre-symptomatic approaches, preventive measures, and data health reforms, which the government is aiming for, and leveraging the knowledge and know-how we have acquired through our generic drug business over many years, we are targeting new businesses in the three fields of digital medical devices business, health food business, and orphan drug business.

In the digital medical devices business, in addition to a non-invasive neuromodulation device to indicate migraines and depression and personal health record (PHR) management app

(see following page), we are undertaking joint development and have concluded a marketing license agreement with CureApp Inc. related to a non-alcoholic steatohepatitis (NASH) treatment app and are preparing clinical trials (phase 3).

Through the health food business, we will provide "foods with functional claims" that support the extension of healthy life expectancy in the life-style disease field, which the Group is particularly strong in. As for the orphan drug business, we are reinforcing our in-house evaluation system and examining the continuous expansion of our pipeline in order to offer new treatment opportunities for diseases lacking effective treatments.



## 1 Non-invasive neuromodulation device SWD001

## Offering a new option for patients who suffer from migraines

In December 2022, Sawai Pharmaceutical applied for approval to manufacture and market SWD001, a medical device used to treat migraines during the acute phase, in Japan. This is a non-invasive neuromodulation device that controls pain by simultaneously stimulating the occipital nerve and trigeminal nerve.

Many Japanese suffer from migraines, and it is expected that the release of this device will increase the number of new treatment options for patients.

#### **Future schedule**

December 2022

2024 Release (target)



The neuromodulation device is expected to broaden acute-phase migraine treatment.

## SaluDi SaluDi Provision of health-related features Main Visualization Linkage with



## 2 PHR management application SaluDi

## Making health management more convenient and intelligent

Released by Sawai Pharmaceutical in October 2021, SaluDi is a personal health record (PHR) management app that makes it possible for people themselves to record and manage their daily state of health. In addition to offering integrated management by recording not only daily health data, such as blood pressure, weight, and body temperature, but also information on food eaten and medicines taken, the app makes it possible to provide telemedicine services and for users to receive dietary instructions by linking to medical facility systems. We will promote its use by local governments, companies, and regional health information networks.

#### Leveraging SaluDi to create a society with health longevity

As Japan's declining population weakens the foundation of mutual support in local communities, we hope that SaluDi can be used to revitalize these communities, such as strengthening bonds between residents and society. We also want to raise

health awareness among individual residents and tie that to the realization of a society with health longevity and healthy aging.

## Hiromichi Adachi

Digital First Section Manager Planning Department, Yabu City



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